UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,854	10/11/2006	Navin N. Thakkar	TKKR-001	5788

26392 7590 03/15/2010

LAW FIRM OF NAREN THAPPETA
C/O LANDON IP, INC.
1725 Jamieson Avenue
ALEXANDRIA, VA 22314

EXAMINER	
HARVEY, JULIANNA NANCY	
ART UNIT	PAPER NUMBER
3733	

NOTIFICATION DATE	DELIVERY MODE
03/15/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

general@IPHORIZONS.COM
lfnt2000@yahoo.com
intercomm@iphorizons.com

Office Action Summary	Application No.	Applicant(s)	
	10/599,854	THAKKAR, NAVIN N.	
	Examiner	Art Unit	
	Julianna N. Harvey	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-29* is/are pending in the application.

4a) Of the above claim(s) *23,28 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-22 and 24-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *Nov. 18, 2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings were received on November 18, 2009. These drawings are acceptable. Accordingly, the objection to Figs. 3A-3E for failure to include a "Prior Art" label is withdrawn and the objection to Fig. 19 for containing a line missing a reference character is withdrawn. However, the objection regarding the reference character "44" is not withdrawn. Even if they are the same part, Applicant is required to name them as such or use different reference characters to correspond to the different names.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "44" has been used to designate both a shaft part and a threaded part. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The abstract of the disclosure is objected to because of improper grammar (the abstract appears to be a machine translation). Correction is required. See MPEP § 608.01(b). The abstract submitted by Applicant on November 18, 2009 is still grammatically incorrect.

The disclosure is objected to because of the following informalities: it is replete with improper grammar (it appears to be a machine translation). Appropriate correction is required. The specification submitted by Applicant on November 18, 2009 is still grammatically incorrect.

Claim Objections

Claims 13-22 and 24-27 are objected to because of the following informalities: the claims are replete with improper grammar (they appear to be a machine translation). Appropriate correction is required.

The previous objection to claims 14 and 16 for failure to further limit claim 13 are withdrawn.

The previous objection to claim 18 for use of “shaft” and “shaft part” is withdrawn.

The previous objection to claims 20 and 22 are withdrawn in view of the amendment to claim 17 positively reciting an end cap.

The previous objection to claim 21 for failure to further limit claim 17 is withdrawn.

The previous objection to claims 24 and 25 for use of “rod" and “intramedullary rod” is withdrawn.

The previous objection to claim 25 is withdrawn in view of the amendment to claim 24 positively reciting an end cap.

The previous objection to claims 25 and 26 for reciting a “proximal fixation device” are withdrawn.

The previous objection to claim 26 for use of “shaft” and “shaft part” is withdrawn.

Claim Rejections - 35 USC § 112

The previous 35 U.S.C. 112, second paragraph rejection of claim 27 is withdrawn.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13, 14, and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Each of these claims recite that the ductility is at least 15% and the ultimate tensile strength is at least 600 MPa. However, Applicant’s disclosure only provides support for a ductility between 15% and 25% and an ultimate tensile strength between 600 MPa and 800 MPa. The examiner also notes

that the original disclosure of PCT/IN2005/000103 is consistent with Applicant's present disclosure, not claims 13, 14, and 17. Accordingly, claims 13, 14, and 17, and claims dependent therefrom, contain new matter.

In the previous Office Action (mailed on June 18, 2009), the examiner indicated that the original disclosure of PCT/IN05/00103 only provides support for a ductility between 15% and 25% elongation, not at least 15% (see page 11 of the Office Action). In response, Applicant pointed to several areas of the present application (see pages 11-12 of Applicant's remarks), none of which recite "at least 15%". Applicant then attempted to indicate that "very high flexibility" means "at least 15%" (see page 12 of Applicant's remarks). However, this is based on Applicant's overly-broad interpretation, not the actual disclosure. If Applicant believes the "at least 15%" limitation is supported, the examiner requests Applicant to point out exactly where such limitation is explicitly recited.

Claim Rejections - 35 USC § 101

The previous rejection of claims 24-27 is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Vicenzi (US 5,281,225 A). Regarding **claim 13**, Vicenzi discloses an orthopedic implant flexible intramedullary nail comprising: a straight flexible nail (8) of universal length being adapted for insertion into a medullary canal of a bone and capable of repositioning and fixing fragments of bones, the nail having two ends (9) and a shaft (area located between two ends) where the ends have a blunt conical pathfinder tip (col. 2, lines 41-42) and the shaft and the ends have flexibility such that the nail is capable of being bowed to any angle or any curvature to adapt to the medullary canal and is capable of maintaining the relation of fragments of bone having multiple contact points of fixation (Figs. 1 and 4). Regarding **claim 15**, Vicenzi discloses that the nail is made from 316L stainless steel (col. 2, lines 37-41). Vicenzi does not explicitly state at least 15% of elongation of the nail on tensile stress and the ultimate tensile strength is at least 600 MPa (**claims 13 and 14**). However, the 15% corresponds to ductility and ductility and tensile strength are properties of a given material. Because the Vicenzi nail is made from the same material as Applicant's invention (316L stainless steel), the examiner is taking the position that the ductility of the Vicenzi nail is at least 15% of the elongation of the nail and the ultimate tensile strength is at least 600 MPa. Therefore, Vicenzi anticipates **claims 13 and 14**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vicenzi (US 5,281,225 A) in view of Walker (US 4,457,301 A). Vicenzi discloses the claimed invention except that the ends are identical. Walker teaches a flexible intramedullary nail (11) wherein the ends (12) are identical blunt ends (Fig. 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Vicenzi intramedullary nail such that the ends are identical, as suggested by Walker, as doing so would simplify assembly of the Vicenzi implant (would eliminate the need for the person assembling the implant to make sure that each individual nail is aligned in the proper direction—top captured end or bottom free end).

Claims 17-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vicenzi (US 5,281,225 A) in view of Walker (US 4,457,301 A) and Ender (US 4,467,793 A). Regarding **claim 17**, Vicenzi discloses an orthopedic implant intramedullary flexible nail assembly adapted for insertion into a medullary canal of long bones comprising: a plurality of flexible intramedullary nails wherein each of the intramedullary nails comprises a straight flexible nail (8) of universal length being adapted for insertion into the intramedullary canal of long bones and capable of repositioning and fixing fragments of bones, the nail having two ends (9) and a shaft (area located between two ends) where the ends have a blunt conical pathfinder tip (col. 2, lines 41-42) and the shaft and the ends have flexibility such that the nail is capable of being bowed to any angle or any curvature to adapt to the medullary canal and is

capable of maintaining the relation of fragments of bone having multiple contact points of fixation; and a proximal fixation device (2) comprising an intramedullary rod having a shaft part, the intramedullary rod having a head portion adaptable to an end cap and temporarily adaptable to a suitable targeting device (threaded hole 5 can receive handle 7 and could also receive a threaded end cap) (Figs. 1 and 4). Vicenzi does not explicitly state that the nail has at least 15% of elongation on tensile stress. However, the 15% corresponds to ductility and ductility is a property of a given material. Because the Vicenzi nail is made from the same material as Applicant's invention (316L stainless steel), the examiner is taking the position that the ductility of the Vicenzi nail is at least 15% of the elongation on tensile stress. Therefore, this limitation of **claim 17** is also satisfied by Vicenzi. Regarding **claim 18**, Vicenzi discloses that the shaft (area located between ends 9) of the proximal fixation device (2) has a hole (4) for receiving an interlocking screw (4a), wherein the hole is placed in either a transverse direction or an angled direction to a long axis of the shaft part of the proximal fixation device to receive the interlocking screw (Fig. 1). Vicenzi fails to disclose that the proximal fixation device has a plurality of longitudinal grooves spaced around a periphery of the intramedullary rod (**claim 17**), an end cap adaptable to the head portion of the intramedullary rod (**claim 17**), that the shaft part of the intramedullary rod has a plurality of holes (**claim 18**), that each of the grooves is less deep than the diameter of one of the flexible nails and the grooves are equally spaced around the periphery of the intramedullary rod for holding the flexible nails apart from one another (**claim 19**), that the intramedullary rod and end cap are made from material comprising one of 316L or 316LVM stainless steel

or other biocompatible material (**claim 20**), and that the intramedullary rod distal end tapers to a blunt point for easy insertion into the medullary canal (**claim 21**). Walker teaches an intramedullary rod proximal fixation device (13) that has a plurality of longitudinal grooves (14) spaced around a periphery of the intramedullary rod fixation device, which is tapered to a blunt point (15) at a distal end (Fig. 2). The grooves of the Walker intramedullary rod fixation device are less deep than the diameter of one of the flexible nails (11) and are equally spaced around the periphery of the intramedullary rod fixation device (Figs. 2-5). Walker teaches that the intramedullary rod is made from biocompatible material (col. 3, lines 34-38). Ender teaches an orthopedic implant assembly wherein flexible nails (4) are held in place by an intramedullary rod (5) having a threaded (21) opening (6) and the opening is covered by a threaded (20) end cap (18) (Figs. 1 and 3). It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the Vicenzi fixation device with the Walker intramedullary rod fixation device (**claims 17, 19, and 21**) as the Walker intramedullary rod fixation device is designed to hold the pins in position to support the fracture during healing (col. 2, line 68 through col. 3, line 3 of Walker). It would have then been obvious to provide the Walker intramedullary rod fixation device with a longitudinal threaded hole (**claim 17**), as suggested by Vicenzi, in order to provide means to insert the fixation device. It would have been obvious to provide the intramedullary rod proximal fixation device with a threaded end cap (**claim 17**), as suggested by Ender, as the end cap can be used to cover the longitudinal threaded hole and prevent tissue ingrowth into the hole. It would have been further obvious to provide the Walker

intramedullary rod fixation device with an angled hole to receive an interlocking screw (**claim 18**), as suggested by Vicenzi, as doing so provides means for fixing the fixation device to the bone. It would have been further obvious to construct the modified Walker intramedullary rod fixation device with a plurality of angled holes (**claim 18**), since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. It would have been further obvious to make the intramedullary rod and end cap from 316L or 316LVM stainless steel or other biocompatible material (**claim 20**), since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. With regard to the limitation "not extending across a fracture zone" (**claim 17**), the examiner notes that this is dependent on a method of use. If the assembly were to be completely assembled outside the body prior to insertion into the body, it would not extend across a fracture zone at that time.

Claims 17 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vicenzi (US 5,281,225 A) in view of Walker (US 4,457,301 A), Haas (US 5,976,140 A), and Grotz (US 5,968,078 A). Regarding **claim 17**, Vicenzi discloses an orthopedic implant intramedullary flexible nail assembly adapted for insertion into a medullary canal of long bones comprising: a plurality of flexible intramedullary nails wherein each of the intramedullary nails comprises a straight flexible nail (8) of universal length being adapted for insertion into the intramedullary canal of long bones and capable of repositioning and fixing fragments of bones, the nail having two ends (9) and a shaft

(area located between two ends) where the ends have a blunt conical pathfinder tip (col. 2, lines 41-42) and the shaft and the ends have flexibility such that the nail is capable of being bowed to any angle or any curvature to adapt to the medullary canal and is capable of maintaining the relation of fragments of bone having multiple contact points of fixation; and a proximal fixation device (2) comprising an intramedullary rod having a shaft part, the intramedullary rod having a head portion adaptable to an end cap and temporarily adaptable to a suitable targeting device (threaded hole 5 can receive handle 7 and could also receive a threaded end cap) (Figs. 1 and 4). Vicenzi does not explicitly state that the nail has at least 15% of elongation on tensile stress. However, the 15% corresponds to ductility and ductility is a property of a given material. Because the Vicenzi nail is made from the same material as Applicant's invention (316L stainless steel), the examiner is taking the position that the ductility of the Vicenzi nail is at least 15% of the elongation on tensile stress. Therefore, this limitation of **claim 17** is also satisfied by Vicenzi. Vicenzi fails to disclose that the intramedullary rod has a plurality of longitudinal grooves spaced around a periphery of the intramedullary rod (**claim 17**), an end cap adaptable to the head portion of the intramedullary rod (**claim 17**), and that the end cap comprises a head part with a plurality of holes to retain a plurality of hooked cut ends of the flexible nails and a shaft part for attachment with the head portion of the intramedullary rod (**claim 22**). Walker teaches an intramedullary rod (13) that has a plurality of longitudinal grooves (14) spaced around a periphery of the intramedullary rod, which is tapered to a blunt point (15) at a distal end (Fig. 2). The grooves of the Walker intramedullary rod are less deep than the diameter of one of the flexible nails

(11) and are equally spaced around the periphery of the intramedullary rod (Figs. 2-5). Haas teaches an end cap (4) with a shaft part designed to be attached to a head portion of an intramedullary rod (2) (Fig. 1). The head part of the Haas end cap extends past the outer periphery of the Haas intramedullary rod (Fig. 1). Grotz teaches an intramedullary rod (2) wherein a cap (3) has a plurality of holes (9) to retain hooked cut ends of a flexible structure (Fig. 4A). It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the Vicenzi fixation device with the Walker intramedullary rod fixation device (**claim 17**) as the Walker intramedullary rod fixation device is designed to hold the pins in position to support the fracture during healing (col. 2, line 68 through col. 3, line 3 of Walker). It would have then been obvious to provide the Walker intramedullary rod fixation device with a longitudinal threaded hole (**claim 17**), as suggested by Vicenzi, in order to provide means to insert the fixation device. It would have been obvious to further modify Vicenzi such that the Walker intramedullary rod proximal fixation device is covered with an end cap having a head part extending past the outer periphery of the intramedullary rod proximal fixation device and a shaft part for attachment with the intramedullary rod proximal fixation device (**claims 17 and 22**), as suggested by Haas, and the head part having a plurality of holes (**claim 22**), as suggested by Grotz, as the end cap can cover the longitudinal threaded hole to prevent tissue ingrowth and act as means to secure the ends of the flexible nails. With regard to the limitation “not extending across a fracture zone” (**claim 17**), the examiner notes that this is dependent on a method of use. If the assembly

were to be completely assembled outside the body prior to insertion into the body, it would not extend across a fracture zone at that time.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vicenzi (US 5,281,225 A) in view of Walker (US 4,457,301 A) and Ender (US 4,467,793 A) as applied to claim 17 above, and further in view of Haas (US 5,976,140 A) and Grotz (US 5,968,078 A). Vicenzi and Walker teach the claimed invention except that the end cap comprises a head part with a plurality of holes to retain a plurality of hooked cut ends of the flexible nails and a shaft part for attachment with the head portion of the intramedullary rod. Haas teaches an end cap (4) with a shaft part designed to be attached to a head portion of an intramedullary rod (2) (Fig. 1). The head part of the Haas end cap extends past the outer periphery of the Haas intramedullary rod (Fig. 1). Grotz teaches an intramedullary rod (2) wherein a cap (3) has a plurality of holes (9) to retain hooked cut ends of a flexible structure (Fig. 4A). It would have been obvious to further modify Vicenzi such that the Walker intramedullary rod is covered with an end cap having a head part extending past the outer periphery of the intramedullary rod and a shaft part for attachment with the intramedullary rod, as suggested by Haas, and the head part having a plurality of holes, as suggested by Grotz, as the end cap can cover the longitudinal threaded hole to prevent tissue ingrowth and act as means to secure the ends of the flexible nails.

Claims 24, 25, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker (US 4,457,301 A) in view of Haas (US 5,976,140 A) and Grotz (US 5,968,078 A). Regarding **claim 24**, Walker discloses an article of

manufacture used to treat bones fractured into a plurality of fragments, where the bone has a medullary canal, the article of manufacture comprising: a proximal fixation device (13) positionable at least partially in the medullary canal and designed to guide insertion of a flexible nail (11) into the medullary canal covering the plurality of fragments, the fixation device also designed to hold the flexible nail in the medullary canal while the fragments heal to form bone, wherein the proximal fixation device comprises an intramedullary rod having a shaft part with a plurality of longitudinal grooves (14), each groove being less deep than a diameter of each of the flexible nails and spaced around the periphery of the rod (Figs. 1-5). Regarding **claim 25**, Walker discloses that the intramedullary rod has a head portion adaptable to an end cap and temporarily adaptable to a suitable targeting device (bore 22 could receive an end cap and a targeting device) and that the intramedullary rod tapers to a blunt point (15) at a distal end (Figs. 2 and 5). Regarding **claim 27**, Walker discloses that the intramedullary rod is made from biocompatible material (col. 3, lines 34-38). Walker fails to disclose an end cap adaptable to the head portion (**claim 24**), that the end cap comprises a head part with a plurality of holes to retain hooked cut ends of the flexible nails and a shaft part adaptable for final attachment with the head portion of the intramedullary rod (**claim 25**), and that the end cap is made from a biocompatible material (**claim 27**). Haas teaches an end cap (4) with a shaft part designed to be attached to a head portion of an intramedullary rod (2) (Fig. 1). The head part of the Haas end cap extends past the outer periphery of the Haas intramedullary rod (Fig. 1). Grotz teaches an intramedullary rod (2) wherein a cap (3) has a plurality of holes (9) to retain hooked cut ends of a

flexible structure (Fig. 4A). Both the Grotz end cap and intramedullary rod are made from a biocompatible material (col. 3, lines 35-36). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Walker intramedullary rod such that it is covered with an end cap having a head part extending past the outer periphery of the intramedullary rod and a shaft part for attachment with the intramedullary rod (**claims 24 and 25**), as suggested by Haas, and the head part having a plurality of holes (**claim 25**), as suggested by Grotz, as the end cap can cover the bore to prevent tissue ingrowth and act as means to secure the ends of the flexible nails. It would have been further obvious to make the end cap from a biocompatible material (**claim 27**), as suggested by Grotz, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. With regard to the limitation "not extending across a fracture zone" (**claim 24**), the examiner notes that this is dependent on a method of use. If the assembly were to be completely assembled outside the body prior to insertion into the body, it would not extend across a fracture zone at that time.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walker (US 4,457,301 A) in view of Haas (US 5,976,140 A) and Grotz (US 5,968,078 A) as applied to claim 24 above, and further in view of de la Caffiniere (US 5,192,281 A). Walker, Haas, and Grotz teach the claimed invention except that the shaft part has a plurality of holes for a plurality of interlocking screws wherein the holes are placed in either a transverse direction or an angled direction to a long axis of the shaft part of the

intramedullary rod to receive the interlocking screws. de la Caffiniere teaches an intramedullary rod (12) designed to hold a flexible nail (14) wherein the intramedullary rod has a plurality of holes (28, 28') angled to the long axis of the intramedullary rod wherein the plurality of holes are designed to receive interlocking screws (30, 30') such that the screws lock the intramedullary rod to bone (Figs. 5-6; col. 2, lines 37-50). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the Walker intramedullary rod with a plurality of holes designed to receive interlocking screws, as suggested by de la Caffiniere, as doing so provides means to lock the intramedullary rod to bone.

Response to Arguments

Applicant's arguments filed November 18, 2009 have been fully considered but they are not persuasive.

Applicant argues that the Vicenzi pin 1 is not of universal length (pages 14 and 17 of Applicant's remarks). The examiner respectfully disagrees. First of all, the claim recites that the nail be of universal length, which in Vicenzi, corresponds to a stem 8. Furthermore, in Applicant's specification, "universal length" is described as:

> "It should be of universal length to have latitude do surgeon to select any fraction length suitable for better fixation and at the same time avoid penetration of proximal epiphysis and avoid irritation of soft tissue at distal end" (para. 004 on pg. 2; emphasis added).
>
> "Invention provides straight flexible intramedullary nail (19) of universal length of 50 cm..." (para. 0026 on pg. 9; emphasis added).

> "As shown in Fig.4A Flexible Intramedullary Nail is straight having universal length preferably of 50 cm..." (para. 0069 on pg. 14; emphasis added).
>
> "Purpose of having universal length is to give surgeon intraoperative latitude to have exact length even in fractions of centimeter, so that upper end do not do injury to epiphysis, at the same time lower end does not irritate soft tissue" (para. 0069 on pg. 14; emphasis added).

None of these describe exactly what "universal length" is. They do not preclude, as Applicant suggests, the surgeon from trimming the ends of the Vicenzi nail, if necessary, to fit the particular patient. In addition, Applicant alleges that "universal length" means that one can use the same length nail in all patients with different lengths of bone in different age groups (pages 14 and 17 of Applicant's remarks). However, this is clearly not realistic when taken in conjunction with the specification (the universal length is preferably 50 cm) because one could not effectively use the same nail in an intramedullary canal of a baby as in an intramedullary canal of a 6-foot tall man (the nail would have to be trimmed to fit in the baby). Furthermore, regardless of whether it would be difficult to glide leading cut ends into the intramedullary canal, as alleged by Applicant, the Vicenzi implant meets the claim limitations at least before the trimming occurs and thus is applicable. Because "universal length" is not adequately explained in the specification to meet Applicant's alleged meaning, the examiner is maintaining the position that the Vicenzi nail is of universal length.

Applicant argues that Vicenzi does not disclose that both ends are identical and free without any attachment and both having a conical pathfinder tip (page 14 and 18 of Applicant's remarks). The examiner respectfully disagrees. First of all, neither the previous Office Action nor this Office Action indicate that the Vicenzi nail has identical

ends. Furthermore, the claim does not recite that both ends are free without any attachment. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that, because the Vicenzi nails 8 are bundled, it is difficult to pass the bundle across the fracture zone without broaching the canal (pages 14-15 and 18 of Applicant's remarks). The examiner respectfully disagrees. Vicenzi states that the nails are provided with temporary retention means to keep the tips together during insertion and to release the tips when the pin is in the correct position (col. 1, ll. 62-68). Applicant's arguments regarding the alleged difficulties of unbundling the nails (pages 15 and 18 of Applicant's remarks) are merely speculation by Applicant.

Applicant argues that it is not possible to align Vicenzi's nails 8 in relation to each other and an individual nail end cannot have a different curvature at different planes to have multiple contact points of fixation (pages 15 and 18-19 of Applicant's remarks). The examiner respectfully disagrees. None of these limitations are present in the claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant agues that the Vicenzi nail does not have a ductility of 15% elongation on tensile stress even though it is made of the same material (316L stainless steel) as Applicant's device (pages 15, 19, and 20 of Applicant's remarks). The examiner respectfully disagrees. Ductility is a property of a given material. Applicant's disclosure

indicates that the nail must have a ductility of 15% elongation on tensile stress and further indicates that the nail can be made of 316L stainless steel. Thus, 316L stainless steel must have a ductility of 15% elongation on tensile stress. Therefore, because Vicenzi's nail is made of 316L stainless steel, it has a ductility of 15% elongation on tensile stress.

Applicant argues that Walker's core and pins that extend across a fracture zone will not be able to have curvatures at different points and planes to get multiple contact points of fixation inside the medullary canal (pages 16 and 19-20 of Applicant's remarks). The examiner respectfully disagrees. Prior to the Walker device being implanted, it does not extend across a fracture zone. Furthermore, if one so desired, one could implant the Walker device in a bone such that it does not extend across a fracture zone. In addition, the claim does not recite curvatures at different points and planes to get multiple contact points of fixation inside the medullary canal. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that Walker's plastic core and metal pins will lead to plastic debris or wear due to friction (pages 16 and 20 of Applicant's remarks). The examiner respectfully points out that the claims do not recite that the core and pins have to be made of the same material. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that Walker does not disclose an end cap (page 16 of Applicant's remarks). The examiner respectfully disagrees. Walker was not relied upon in neither the previous Office Action nor this Office Action to provide teaching for an end cap.

Applicant argues that Walker teaches a sliding fit of the pins in the grooves of the core and alleges that this allows sliding and migration of pins and also alleges that Walker teaches keeping pins outside the core without any anchorage with the core (pages 16-17 of Applicant's remarks). The examiner respectfully disagrees. Nowhere does Applicant claim that the pins cannot be slid into position in the core. Just because the pins are slid into position in the core does not mean that sliding and migration of the pins are allowed to occur. Furthermore, nowhere does Walker state that the pins cannot be anchored to the core, as alleged by Applicant. Col. 3, ll. 53-56, cited by Applicant, states "Normally, the driven ends of the pins and core are not forced all the way into the bone. Enough of each is left exposed so that their ends can be gripped when removal is indicated." This has nothing to do with anchorage of one component to another.

Applicant argues that combining Walker with Vicenzi will not be able to allow having curvatures at different points and planes to get multiple contact points of fixation inside the medullary canal (page 20 of Applicant's remarks). The examiner respectfully disagrees. The claim does not recite curvatures at different points and planes to get multiple contact points of fixation inside the medullary canal. Although the claims are

interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that the examiner has speculated that the bore 22 of Walker could receive an end cap and targeting device (page 21 of Applicant's remarks). The examiner respectfully disagrees. The claim recites that the head portion be temporarily adaptable to a targeting device and that the end cap have a shaft part adaptable to the head portion. A bore can be temporarily adaptable to a targeting device (a driver, a guidewire, etc. can be received in a bore). The examiner relied upon Haas to show an end cap that has a shaft part that is received in a bore, thus showing that the bore of Walker is able to receive an end cap.

The examiner is unsure what Applicant's following argument means. The examiner asks Applicant to clarify so she can appropriately respond.

> "Even if such modification of Walker's fixation device having plastic flexible core 13 adaptable securely to targeting device is done and intended for use with such structural limitation, targeting of possible plural holes in such fixation device by targeting device would not be accurate due to very high flexibility of plastic core relative to pins, angles and adjustment with targeting device will change due deflection of plastic core within medullary canal of a bone (for example femur)." (page 21 of Applicant's remarks)

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julianna N. Harvey whose telephone number is 571-270-3815. The examiner can normally be reached on Mon. - Fri., 6:30 a.m. - 2:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. N. H./
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733